K012020

APPENDIX G 510(k) Summary

AUG 2 1 2001

510(k) Summary
For
Non-Invasive Monitoring Systems, Inc.
RespiEvents™ software, Version 5.2

DATE THIS SUMMARY WAS PREPARED: June 24, 2001

SUBMITTER'S NAME AND ADDRESS:

Non-Invasive Monitoring Systems, Inc.
1840 West Avenue
Miami Beach, Florida 33139

CONTACT PERSON:

Allan F. Brack, Chief Executive Officer
Telephone: (305) 534-3694
Facsimile: (305) 534-9368

DEVICE NAME:

Proprietary or Trade Name:	RespiEvents™ software, Version 5.2
Common Name:	Event data processing software for a PC
Classification Name:	Programmable Diagnostic Computer

PREDICATE DEVICE:

The legally marketed device to which equivalence is claimed is:

RespiEvents™ software, Version 4.2, K001369, cleared on July 26, 2000.

- Product Code: 74 DQK
- CFR Section: 870.1425

DEVICE DESCRIPTION:

RespiEvents™ is a software analysis program running on a personal computer. RespiEvents™ presents waveforms collected from RespiTrace™ technology-based recorders such as Respitrace Plus™ and RespiTrace PT™ and is intended to provide analysis of:

- Breathing patterns from Respitrace™ technology,
- Aid in identifying and classifying apneas,
- Displaying heart rate changes from electrocardiographic waveforms,
- Logging values from pulse oximetry, and
- Displaying signals from physiologic recording devices

The purpose of RespiEvents™ software is to capture full fidelity Respitrace™ data on a continuous basis, and to provide playback and analysis of the captured data.

The system presents the information from physiologic recording devices such as a body position sensor and impedance pneumograph, in the wake and sleeping states. The system does not present alarms, alarm functions, or alarm management.

INTENDED USE:

RespiEvents™ is a software package running on a personal computer that is intended to provide analysis of breathing patterns from RespiTrace technology, aid in identifying and classifying apneas, displaying heart rate changes from electrocardiographic waveforms, logging values from pulse oximetry, and displaying signals from physiologic recording devices such as a body position sensor and impedance pneumograph, in the wake and sleeping states as well as activities of daily living.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS:

This submission is for modifications to the RespiEvents™ software, version 4.2 that was cleared for marketing under Premarket Notification K001369. The RespiEvents™ software, version 5.2 is a modification to the predicate device which does not change the intended use or the fundamental scientific technology.

The RespiEvents™ software has been modified to operate on PC running Microsoft Windows 95 or 98 and presents the user with an ergonomically acceptable typical Windows User Interface. The software also has several re-named traces for greater user clarity. No modifications were made to the core software, algorithms, or fundamental scientific technology.

NONCLINICAL TESTS USED IN DETERMINATION OF SUBSTANTIAL EQUIVALENCE:

The new software has undergone complete verification and validation test scenarios to show that all functions are in compliance with the user requirements, safety standards, and performance specifications. This involved the use of simulated input signals, manual operations and recordings of actual physiological waveforms.

CONCLUSIONS FROM NONCLINICAL TESTING:

The testing of the RespiEvents™ software, version 5.2 demonstrates the performance is substantially equivalent to the predicate device. When used in accordance with the directions for use, by qualified personnel, RespiEvents™ software, version 5.2, is safe and effective, as indicated, for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 1 2001

Mr. Allan F. Brack
Chief Executive Officer
Non-Invasive Monitoring Systems, Inc.
1840 West Avenue
Miami Beach, FL 33139

Re: K012020
Trade Name: RespiEvents™ Software, Version 5.2
Regulation Number: 21 CFR 870.1425
Regulatory Class: II (two)
Product Code: 74 DQK
Dated: August 3, 2001
Received: August 6, 2001

Dear Mr. Brack:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4645. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

APPENDIX B INDICATIONS FOR USE STATEMENT

RespiEvents™ software, version 5.2 Indications for Use

510(k) Number: K012020

Device Name: RespiEvents™ software, version 5.2

Indications for Use: RespiEvents™ is a software package running on a personal computer that is intended to provide analysis of breathing patterns from RespiTrace technology, aid in identifying and classifying apneas, displaying heart rate changes from electrocardiographic waveforms, logging values from pulse oximetry, and displaying signals from physiologic recording devices such as a body position sensor and impedance pneumograph, in the wake and sleeping states as well as activities of daily living.

This is the same intended use as most recently cleared for the NIMS RespiEvents DOS software, version 4.2, 510(k): K001369, dated July 26, 2000.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use___X___ **OR** **Over-The-Counter Use_____**
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K012020